

INFORMATION PAPER

MILVAX - VHCN
4 December 2013

SUBJECT: Hepatitis B Infection and Hepatitis B Vaccines

1. Purpose. To describe hepatitis B virus and the vaccines to prevent it.

2. Facts.

a. Microbiology. Hepatitis B virus (HBV) is a non-enveloped, partially double-stranded DNA virus in the hepadnaviridae family. The life cycle of an HPV virus begins with attachment of the viral cell to the host cell which is generally the liver cells. HPV infection begins when the relaxed circular viral DNA (rcDNA) is brought into the nucleus where it is repaired to the covalently closed-circular form (cccDNA). This step is essential and is a prerequisite for the establishment of a productive infection by hepadnaviruses, since cccDNA is the central template for viral transcription and replication. The virus contains multiple antigenic components and there is no apparent difference in infectivity or virulence of the subtypes. HBV is particularly tenacious and, in some instances, remains infectious on surfaces for more than 7 days.

b. Disease. The incubation period for HBV ranges from 6 weeks to 6 months and averages 120 days. HPV replicates in the liver and causes hepatic dysfunction. Clinical symptoms occur more often in adults than infants or children, who are usually asymptomatic. Initial symptoms may include loss of appetite, diarrhea, vomiting, redness, jaundice (yellow skin or eyes) and pain in the muscles, joints, and stomach. At onset of jaundice a change in stools, liver tenderness and swelling may be noted. Approximately 5% of all acute HBV infections will result in chronic HBV infections. Chronic infections are responsible for most cirrhosis (scarring of the liver), liver cancer, liver failure, and even death.

c. Epidemiology. Humans are the only natural reservoir of the virus and transmission occurs by contact with contaminated secretions, including semen, vaginal secretions, blood, and saliva; through percutaneous inoculation (e.g., accidental needle sticks or sharing of needles with infected people); or by maternal-neonatal transmission. About 1/3 of people who are infected with the hepatitis B virus in the United States are unaware of it. At-risk groups include: people traveling to high-risk areas; healthcare personnel; laboratory workers handling blood and body fluids; people with diabetes; police, fire and emergency medical personnel who give first-aid treatment; people with blood-clotting disorders (e.g., hemophilia); people who have household contacts infected with the virus; people with multiple sex partners; men who have sex with men; and people who have a sexually transmitted disease. Hepatitis B vaccine is 80% to 95% effective in preventing HBV infection and clinical hepatitis among susceptible children and adults. If a protective antibody response develops after vaccination, vaccine recipients are virtually 100% protected against clinical illness.

d. Vaccine.

(1) COMVAX[®] produced by Merck is a pediatric combination vaccine that contains Hep B and Hib. It should not be used for the Hep B birth dose. The vaccine is preservative free.

(2) PEDIARIX® produced by GlaxoSmithKline is a pediatric combination vaccine that contains DTaP-Hep B-IPV. The prefilled syringe tip caps and rubber stopper may contain latex. The vaccine is preservative free.

(3) TWINRIX® produced by GlaxoSmithKline is an adult bivalent vaccine of inactivated hepatitis A virus and the purified surface antigen of the hepatitis B virus. The prefilled syringe tip caps and rubber stopper may contain latex. All formulations of the vaccine are preservative free.

(4) Engerix-B® produced by GlaxoSmithKline has both pediatric and adult formulations. The prefilled syringe tip caps and rubber stopper may contain latex. All formulations of the vaccine are preservative free.

(5) Recombivax-HB® produced by Merck has pediatric, adult, and dialysis formulations. The prefilled syringe tip caps and rubber stopper may contain latex. All formulations of the vaccine are preservative free.

e. Immunization.

(1) Routine infant vaccination occurs at birth, 1-2 and 6-18 months after the initial dose. People typically receive three intramuscular doses over a 6- to 12-month period. The second dose should be given 1 month after the first dose; the third dose should be given at least 2 months after the second dose and at least 4 months after the first dose.

(2) The dosage is age and brand dependent. See each vaccine's recommended dosage and administration schedule, which are based on maternal hepatitis-B infection status, age, and individual's health condition (e.g., hemodialysis, diabetes). Review the Advisory Committee on Immunization Practices (ACIP) guidelines for unique requirements for serology testing of individual's pre and post vaccination.

(3) See the additional information paper on completing vaccine series with either Hep A/Hep B combination vaccine or the monovalent hepatitis A and hepatitis B vaccines at: www.vaccines.mil/documents/1504MIP-Hep%20A-B%20Counting%20Doses.pdf

f. Cautions. The following people should not receive hepatitis B vaccine: those with known severe hypersensitivity to the vaccine or to one of its components (e.g., yeast); those who have a moderate to severe acute illness. Review the package insert for full precautions and contraindications for each vaccine.

g. Adverse Events. The most common adverse reactions after hepatitis B vaccination are irritation, redness, swelling, warmth, itching, and bruising at the injection site; and mild systemic complaints include headache, fever, myalgia, and malaise. More rare serious reactions include tingling of the hands or feet, difficulty moving, stiffness, skin rash, difficulty breathing, chest pain, or vision problems.

h. DoD Policy. Unless seroimmune, administer hepatitis A vaccine to military personnel at initial entry training or upon deployment to HAV endemic areas.

3. References.

a. Centers for Disease Control and Prevention. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Part I. MMWR 2005; 54(RR-16):1- 23.

b. Centers for Disease Control and Prevention. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP). Part II. MMWR 2006; 55(RR-16):1- 33.

c. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by MILVAX - VHCN: www.vaccines.mil/HepB

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